

Exhibit 9

(Part II)



CASE 3528

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of :
DAVID C. HECKERT :
Serial No. 860,607 : Group Art Unit 132
Filed May 7, 1986 :
FRUIT JUICE BEVERAGES
AND JUICE CONCENTRATES
NUTRITIONALLY SUPPLEMENTED WITH CALCIUM

DISCLOSURE STATEMENT PURSUANT TO 37 CFR 1.56, 1.97 AND 1.98

The Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

In accordance with 37 CFR 1.56, 1.97 and 1.98, Applicant requests that the Examiner make of record the documents listed on the attached PTO-1449 form. Copies of these documents (including English translations) are also enclosed. The enclosed English translations are believed to be accurate. However, Applicant makes no warranty as to their complete accuracy.

The Examiner may wish to consider these documents in the examination of the above application. No representation is made or intended that the search which led to these documents was complete and thorough, or that more relevant documents do not exist. The presentation of these documents is not an admission of any kind, and is particularly not an admission that any of these documents are properly citable against the above application.

These documents are grouped and presented below in what is believed to be the order of relative pertinence. All comments which follow are also believed to be a fair representation or characterization of each document. However, the following comments should not be substituted for the Examiner's complete consideration of each document.

U.S. Patent 2,325,360 (Reference AA), discloses a method for replacing gases removed during deaeration of fruit juices, such as orange juice, with carbon dioxide. In this method, dry calcium carbonate, or a mixture of calcium carbonate and citric acid, is dropped into a can which is then filled with deaerated orange juice. (Other organic acids such as malic and tartaric acid can be used in place of citric acid.) The reaction between the calcium

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carbonate and added citric acid, or citric acid in the juice, generates the carbon dioxide.

U.S. Patent 3,657,424 (Reference AB), discloses the fortification of citrus juices, including orange juice, with sodium, calcium and chloride ions in amounts beyond what is naturally present in the juice. Calcium salts which can be used in fortification include the chlorides, citrates or phosphates, although calcium chloride is preferred for providing the desired chloride ion. The maximum amounts of calcium salts permitted in these fortified citrus juices is up to about 0.04%. (This calculates to about 0.015% calcium in the juice if calcium chloride is used.) The citrus juices fortified can be single-strength, diluted or frozen concentrates.

U.S. Patent 3,114,641 (Reference AC), discloses extended orange juice products obtained by diluting single-strength orange juice or concentrated orange juice. To maintain the flavor of the diluted orange juice product, materials such as calcium chloride, magnesium chloride, sodium or potassium citrates, tartaric and malic acids (or their salts) are included in "very small amounts." These extended orange juice products are based on a dilution factor of 1:1 to 1:4 when single-strength juices are used or 1:12 to 1:16 when concentrated juices are used. The one example given of an additive formula for use with these extended products contains calcium chloride (0.04%), citric acid (0.85%) and sodium citrate (0.06%). This additive formula can be added directly to the single-strength juice or concentrate, the water used to make the extended product, or to the extended product itself.

British Patent Specification 2,095,530, (Reference AL), discloses a process for obtaining an acid beverage enriched in protein, particularly a fruit juice or fruit-flavored beverage. In this process, an aqueous suspension of soy protein is prepared using water and/or fruit juice. Calcium in a concentration of from 5 to 50mM is added, after which the pH of the suspension is reduced and the insoluble material separated to yield a protein solution. A fruit juice or fruit flavoring can then be added to this protein solution. The calcium can be added in the form of the chloride, acetate, tartrate, malate or lactate salt, although calcium chloride appears to be preferred. The beverage described in Example II, which uses orange juice as the extraction medium, has 30mM of calcium added.

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European Patent Application 75,114, (Reference AM), discloses protein-containing fruit juice drinks enriched with vitamins and minerals. These drinks contain 30-90% fruit juice (a mixture of 20-70% apple juice, 4-40% white grape juice, 1-10% passion fruit juice and 5-25% lemon juice), 2 to 20% whey protein concentrate, and a mineral salt mixture of potassium, sodium, magnesium, calcium and phosphate. Calcium is present in these drinks at 0.01 to 0.3%, preferably at 0.02 to 0.03%. These drinks can be prepared by combining a first solution of apple, passion fruit and grape juice containing the whey concentrate with a second aqueous solution of lemon juice containing the mineral salt mixture. The calcium salts used in this mineral salt mixture are not specified.

U.S. Patent 4,551,342 (Reference AB), discloses beverages containing specific mixtures of cations (calcium, potassium and magnesium), as well as specific mixtures of acids (citric, malic and phosphoric acid), to provide desirable flavor impressions, in particular body, while being stable against precipitation of insoluble salts, in particular calcium salts. The flavor component of these beverages can comprise a fruit juice such as orange, lemon and lime juice. When fruit juice is used, the flavor component can comprise from about 5 to about 50% by weight, preferably from about 5 to about 10% by weight, of the beverage.

Japanese Patent Document 54-8767 (Reference AN), discloses a calcium enriched soft drink containing salts of food organic acids such as calcium citrate, calcium malate, calcium lactate, calcium tartrate, and so on. One such soft drink consists of 3 parts of a mixture of calcium citrate, calcium malate and calcium lactate, 3 parts of a mixture of fruit sugar and invert sugar, 4 parts of a mixture of orange juice and lemon juice, and 90 parts water.

U.S. Patent 3,723,133 (Reference AE), discloses a citrus product prepared from deacidified orange juice which is dehydrated and then blended with high-acid products. The deacidified product is prepared by obtaining a single-strength orange juice or other citrus juice, centrifuging to remove suspended solids, neutralizing the clarified supernatant with calcium or other suitable metal hydroxide, recentrifuging to remove the precipitate calcium citrate or other metal citrate, recombining with the originally removed suspended solids, concentrating the deacidified whole juice and then dehydrating the resultant concentrate.

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U.S. Patent 4,078,092 (Reference AF), discloses apple juice compositions which comprise milk, apple juice, sodium carboxymethylcellulose, and acid such as citric acid or lactic acid, with or without coloring agent, fruit essence, seasonings and/or water.

Applicant also requests that the Examiner consider and make of record the following copending U.S. applications:

U.S. applications Serial No. 813,744, filed December 26, 1985 and Serial No. 860,726, filed May 7, 1986 to Nakel, Russell, Dake and Heckert, disclose beverages and beverage concentrates nutritionally supplemented with calcium (0.06 to 0.15% for beverages, 0.2 to 0.75% for concentrates) which can contain up to 40% fruit juice on a single strength basis. Embodiment 1 describes a fruit juice containing beverage syrup prepared by dissolving equal amounts of malic and citric acid in water, adding calcium carbonate and then high fructose corn syrup to the acid solution, and finally adding apple juice concentrate having a solids content of 72.1° Brix. This beverage syrup was mixed with carbonated water to form a carbonated beverage.

Respectfully submitted,

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LIST OF DOCUMENTS CITED BY APPLICANT(S)

(Use several sheets if necessary)

APPLICANT

David C. Heckert

FILING DATE

5/7/86

GROUP

132

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	2 3 2 53 6 0	7/43	Ayers et al			
AB	3 6 5 74 2 4	4/72	Atkins et al			
AC	3 1 1 46 4 1	12/63	Sperti et al			
AD	4 5 5 13 4 2	11/85	Nakel et al			
AE	3 7 2 3 1 3	3/73	Berry et al			
AF	4 0 7 80 9 2	3/78	Nishiyama			
AG						
AH						
AI						
AJ						
AK						

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
AL	2 09 5 53 0	10/82	Great Britain			
AM	7 5 11 4	3/83	Europe			
AN	5 4- 8 7 67	1/79	Japan			
AO						
AP						

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	
AS	
AT	

EXAMINER

Carolyn Padu

DATE CONSIDERED

11/25/86

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DCH

Translation of: European patent application 0 075 114
Filed: August 19, 1982
Published: March 30, 1983
Priority: September 21, 1981 DE 3 137 440
Patentee: Firma Peter Eckes

Title: Protein-containing conditioning drink

The present invention concerns a protein-containing conditioning drink based on a mineral- and vitamin-enriched drink with a high proportion of fruit juice. By a conditioning drink is to be understood a drink which regulates in a natural manner the body's performance capacity, and which is suitable in the same way for athletes and hobby athletes. For this purpose, a whole series of different types of drinks have already been used, drinks which, in part, are mixed directly by the trainers or the athletes themselves.

On playing fields, for example, there are distributed aqueous salt solutions, which compensate for salt loss to be observed with lengthy physical performance, especially at high outside temperatures. Such drinks occasionally have added soluble vitamins or else substances such as grape sugar. For taste improvement, such drinks are occasionally also mixed with fruit juices, whereby they are similar to common refreshing drinks based on fruit juice.

For nutrition-physiological reasons, it would be desirable if proteins could also be added to such a drink, without losing the character of a refreshing drink in the resulting drink.

A number of experiments have already been undertaken to enrich drinks with extra proteins. As long as they have the character of milk drinks, no problems result. In cases of refreshing drinks based on vegetables or especially fruit juice, the incorporation of proteins into such drinks however is connected with difficulties, since such drinks have an acid pH, which has the result that the proteins of many of the protein additives used in the food technology sector do not remain in solution, but are precipitated out. To be sure, there are known proteins which are soluble in the acid range under normal conditions. No one has previously been successful, however, in finding among such proteins one which could be incorporated into a conditioning drink, since either the characteristic taste of the protein additive used was not compatible with the character of a refreshing drink simultaneously being sought, or the proteins have proven to be insufficiently stable for the heating necessary for the drink production.

Only in the case of an aqueous drink based on tomatoes with a pH between 4.0 and 4.5 was there found a protein composition which corresponded with respect to taste to the special character

of such a drink and which yielded a sufficiently stable solution (vgl. DE-OS 25 05 717). This protein composition was a mixture of certain meat proteins with a partially-hydrolyzed soy protein. The possibility of use of such a protein composition is traced in part to a solution-stabilizing special effect of the tomatoes used.

For the incorporation in drinks based on fruit juice, these proteins proved unsuitable, as did about 80 other protein samples investigated, such as, for example, various soy proteins, milk proteins, meat proteins, blood albumin, egg white, potato protein, algal proteins, cottonseed protein, fish protein, KK-proteins.

The invention has as a basis the problem of producing a protein-enriched conditioning drink, which is similar, taste-wise, to common drinks based on fruit juice, and thus is suitable to succeed as a daily drink even for hobby athletes, and can be produced on a large scale made stable through pasteurization, similar to common fruit juices and nectars. It should also be characterized by sufficient stability, as well as by a good tolerance, which is a prerequisite for prevention of a loss in physical performance capacity.

This problem is solved according to the invention by a protein-containing conditioning drink based on a mineral- and vitamin-enriched fruit-juice-containing drink, which is characterized in that it consists of a proportion of 30 to 90 wt.-% of a fruit juice or a mixture of different fruit juices, corresponding to a solid content of 4 to 20 wt.-%, a proportion of 2 to 20 wt.-% of a whey concentrate, corresponding to a content in whey protein of 1.2 to 5 wt.-%, where the content of whey concentrate in lactose was previously split enzymatically and/or of partially-hydrolyzed soy protein, as well as a natural rounding-out aromatization, mineral salts and optionally additional water, as well as an addition of vitamins, where such a drink has a pH between 4.0 and 5.0.

It was surprising that it was proven in the investigations that, for the production of a conditioning drink with the desired properties of a refreshing drink with a high fruit juice proportion, commercially-available whey concentrates are suitable, when the amount of lactose commonly present in these whey concentrates has previously been split, before preparation of the drink, enzymatically as much as possible into the constituents of lactose, glucose and galactose. It could not be calculated that such whey concentrates, whose content in whey protein customarily lies in the range of 9 to 30 wt.-%, would be suitable for the conditioning drinks according to the invention. That is, it was known that the whey proteins present in the cold in the form of a solution have an isoelectric point of about 4.6, and that they coagulate at this pH upon heating. Since fruit-juice-containing

drinks very frequently have a pH between 4.0 and 5.0, thus form the ideal medium for the precipitation of whey proteins upon heating, it must therefore be calculated that, during the final pasteurization and holding at a high temperature necessary in the drink production, the added proteins would precipitate, at least partially. Surprisingly, however, this was not the case, when the lactose content of the whey concentrate had previously been split enzymatically and also a mixture with fruit juices in the amounts given above was selected. It seems to be such that, on the one hand, the special protein used behaves otherwise than expected, and that possibly also the quantitative composition of the entire drink, that is, also the proportion in fruit juice and optionally also the proportion in mineral salts, acts in a stabilizing manner.

It was furthermore determined that the special protein used, in combination with the simple sugars produced during the enzymatic splitting, does not influence or interfere with the fruit juice taste of the drink, so that the resulting conditioning drink is very palatable. It also proved to be stable, without occurrence of the taste changes frequently to be observed, and was, in addition, also very well tolerated. An especially favorable conditioning drink, from every point of view, is thus obtained, when the content in whey protein lies between 1.5 and 3.5 wt.-%. The sweet whey concentrate is preferred as the whey concentrate. It is also advantageous to assure that, in the enzymatic splitting of the lactose, the residual content in unsplit lactose lies at values between 3.5 and 7%. The preferably liquid whey concentrate can be partially or totally replaced by partially-hydrolyzed soy protein, especially when a reduction of the sugar content is desired.

An especially advantageous conditioning drink also contains, as the fruit juice components, a mixture of the following fruit juices in the amounts given for each in weight percent:

Apple juice	20 to 70 wt.-%,
Passion fruit juice	1 to 10 wt.-%,
Grape juice (white)	4 to 40 wt.-%, and
Lemon juice	5 to 25 wt.-%.

Especially preferred ranges for the amount proportions of the fruit juice components named lie, for apple juice, between 25 and 40 wt.-%, for passion fruit juice, between 3 and 5 wt.-%, for grape juice (white), between 10 and 20 wt.-% and for lemon juice, likewise between 10 and 20 wt.-%. For the especially advantageous conditioning drinks mentioned, the pH lies at 4.3. Besides a natural rounding-out aromatization of 1 to 10%, preferred 3 to 5%, as well as additional water in an amount of 0 to 70 wt.-%, preferred 10 to 30 wt.-%, the conditioning drink according to the invention also contains mineral salts as well as an addition of vitamins. The mineral salt mixture used is a mixture of

physiologically-important mineral salts, which are present in the drink advantageously in the following amounts:

K ⁺	0.028 to 0.28 wt.-%, preferred 0.12 - 0.15 wt.-%;
Na ⁺	0.028 to 0.28 wt.-%, preferred 0.12 - 0.15 wt.-%;
Mg ²⁺	0.002 to 0.08 wt.-%, preferred 0.008 - 0.015 wt.-%;
Ca ²⁺	0.01 to 0.3 wt.-%, preferred 0.02 - 0.03 wt.-%;
<u>and, as anion,</u>	
PO ₄ ³⁻	0.006 to 0.5 wt.-%, preferred 0.08 - 0.1 wt.-%.

In all cases, the data in weight percent refer to a volume part of the entire conditioning drink according to the invention. With adequate approximation, then, a liter of conditioning drink can be equated with 100 weight percent ca. 1050 to 1100 g.

Vitamins are also added to the conditioning drink. For the addition of vitamins to foodstuffs, there exists a regulation about foods with added vitamins. Several or all permitted vitamins are preferably added to the conditioning drink according to the invention, in amounts of the daily requirements recommended by the DGE, where, of course, a certain experimentally-determined overdose is selected, which is necessary in order to compensate for stability of the vitamins, which is not sufficient in all cases, so that the finished drink contains, in 0.2 l, the recommended daily requirement in added vitamins, even after a long storage. As seen from a grouping of the examples above, a conditioning drink according to the invention, in its preferred form, has a composition according to the values given in Table 1.

Table 1

	Range	Preferred
Apple juice	20-70%	50-65%
Passion fruit juice	1-10%	3- 5%
Grape juice (white)	4-40%	10-20%
Lemon juice	5-25%	10-20%
Whey protein, liquid conc., in which the milk sugar is split	2-20%	11-17%
Natural rounding-out aromatization	1-10%	3- 5%
Water	0-70%	0-30%
K ⁺	0.028-0.28%	0.12-0.15%
Na ⁺	0.028-0.28%	0.12-0.15%
Mg ²⁺	0.002-0.08%	0.008-0.015%
Ca ²⁺	0.01-0.3%	0.02-0.03%
P	0.006-0.5%	0.08-0.1%
pH	4.2-4.4	4.3

In addition to the components given, vitamins are added, in accord with the specifications legal for foods.

The production of the conditioning drink according to the invention preferably takes place in such a way that, separate from one another, first a mixture of the whey hydrolysate with apple juice and the passion fruit juice and grape juice is produced, and parallel to this, a second mixture is produced, which is a mixture of water and lemon juice, in which, in a certain sequence, the mineral salts, that is the sodium salt, the magnesium salt, the calcium salt and the potassium salt, are introduced and to which also the vitamin mixture is added. This second mixture is then added, under stirring, to the fruit mixture with the whey hydrolysate, after which the rounding-out aromatization takes place. After the finished mixture is produced, it is pasteurized, drawn off hot and, after a time of holding at high temperature, then re-cooled. Up until the drawing off, the mixture should not exceed a standing time of 4 hours. If an addition of water takes place, de-salted water is preferably used.

The precise process for the production of the conditioning drink according to the invention is to be inferred from the following example, in which the production of an especially preferred conditioning drink according to the present invention is further illustrated.

Example

For the production of 1 liter of a conditioning drink according to the present invention, proceed as follows:

Under stirring, for example with a radius vector?(unsure of translation) mixer, 150 ml of a liquid whey concentrate, which has a content of about 12 wt.-% sweet whey protein and whose content in lactose has previously been split into glucose and galactose in known manner through enzymatic hydrolysis with one of the known enzymes suitable for splitting disaccharides, for example with lactase, up to a residual content of 3.5 to 7% lactose, are dissolved in 300 ml of apple juice in such a way that neither a residue nor a deposit is obtained. Then there follows, under constant stirring, the addition of 30 ml of passion fruit and finally, under continued stirring, 150 ml of a white grape juice are added. During the entire mixing process for production of the solution mentioned above, the temperature of the liquid is controlled so that it does not exceed a maximum value of 15°C.

Parallel to the preparation of the first solution, a second solution is prepared by adding to 180 ml water enough lemon juice so that the pH is 2.5 to 2.7 (ca. 150 ml). Then the mineral salts, very finely ground to the same extent, are added in small amounts, very slowly, under constant stirring, in order to avoid irreversible

lump formation. The mixture consists of sodium salt with a content of 1.4 g Na⁺ ions, magnesium salt with a content of 0.1 g Mg²⁺ ions, calcium salts with a content of 0.26 g Ca²⁺ ions and potassium salt with a content of 1.4 g of K⁺ ions. The salts are selected so that 0.9 g phosphate is simultaneously introduced into the solution. When all salts have completely dissolved, and a homogeneous solution is obtained, this is cooled to a temperature of at least 20°C. Then to the second solution, obtained in this way, is added a mixture of all vitamins approved for vitamin-enriched foods. The mineral/vitamin mixture in water and lemon juice prepared separately as described above is added, with stirring, to the first solution, that is, to the fruit mixture. After the two solutions are homogeneously mixed, a rounding-out aromatization is undertaken, with which once again about 50 g of plant extracts are introduced into the mixture. For this, one must take care that the temperature of the mixture never exceeds a maximum value of 15°C.

The drawing off takes place in such a way that the finished mixture is pasteurized at temperatures between 75 and 90°C, then drawn off at a temperature of 83 to 87°C in the hot condition and, after holding in the hot state for 5 to 20 minutes, is recooled.

The resulting product has a pH of 4.3 and contains the individual constituents in the following amounts:

Apple juice	30	%
Passion fruit juice	3	%
Grape juice (white)	15	%
Lemon juice	15	%
Liquid whey concentrate		
(Content in whey protein corresponding to 2%)	15	%
Natural rounding-out aromatization	5	%
De-salted water	18	%
Mineral salts: K ⁺	0.14	%
Na ⁺	0.14	%
Mg ²⁺	0.01	%
Ca	0.026	%
P	0.09	%

Vitamins per l : 5-times the daily requirement
recommended by the DGE plus
an overdose necessary for stability
reasons

The resulting product is a liquid, stable with respect to turbidity, with very pleasant sensory properties, that is, with a pleasant, fruity taste and of a pleasant consistency, in spite of the relatively high solid content, which makes it a palatable drink with the character of a refreshing drink.

LAID-OPEN PATENT JOURNAL, Sho 54-8767, January 23, 1979

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- 54: Calcium enriched soft drink
- 21: Patent application - Sho 52-69999
- 22: Date of application - June 15, 1977
- 72: Inventors - Hisaji Kaji and one other
22-20-6, Kitakarasuyama Setagaya-ku Tokyo-to
- 71: Applicants - Hisaji Kaji and two others
22-20-6, Kitakarasuyama Setagaya-ku Tokyo-to
- 74: Representative - Patent attorney Michizo Isono
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Specification

1. Title of invention
Calcium enriched soft drink
2. Claim
Calcium enriched soft drink containing calcium salts of food organic acids such as calcium citrate, calcium malate, calcium lactate, calcium tartarate, etc.

3. Detailed explanation of the invention
The present invention refers to a calcium enriched soft drink containing food organic acids such as calcium citrate, calcium malate, calcium lactate, calcium tartarate, and so on.

As the conventional well known soft drinks, there are carbonate drinks such as ramune (lemonade), cider (an aerated cider-like drink), tansan (carbonate), cola, etc.; fruit juice drinks such as fruit juice, fruit juice molasses, water containing fruit juice, etc.; lactic acid drinks such as calpis, yakuruto, etc.. Raw materials of manufacturing the said drinks are soft water containing small amounts of iron, manganese, chlorine, etc.; sweeteners such as refined white sugar, invert sugar, etc.; flavoring agents such as essence, extract, etc.; souring agents such as citric acid, tartaric acid, lactic acid, etc.; food colors such as caramel, etc.; and so on. These drinks are used regularly as some energy supplying sources between meals, water supplier, thirst reliever, digestion promotor, and so on., and the production of such drinks are increasing year after year. However, the sugar content in these drinks create some problems from the nutritional point of view. In other words, an excess intake of sugar causes an accumulation of metabolic intermediates including methylglyoxal, pyruvic acid, lactic acid, etc., which are incomplete combustion products. As a result, an accumulation of these intermediates in blood turns the blood into acidic pH. In order to neutralize the pH, calcium from bone, teeth, etc. is eluted. On the other hand, the body becomes acidosis which weakens the body's resisting power against bacteria and triggers various diseases. Furthermore, the recent dietary life tends to intake excess sugar. In spite that growing

children and infants require a large amount of calcium, frequent intake of soft drinks and candies creates medical problems, especially this has caused an rapid increase in dental problems (carious tooth).

However, the present invention on soft drinks was accomplished under the consideration of problems described above. In other words, the soft drink in the present invention was prepared by adding calcium salts of food organic acids such as calcium citrate, calcium malate, calcium tartrate, calcium lactate, etc., which are helpful in the catabolism including citric acid cycle, to raw materials such as water, fructose, invert sugar, fruit juice, vegetable extract, etc.

One of many methods of manufacturing the calcium enriched soft drinks described in the present invention and the method of preparing calcium salts of food organic acids are explained in the following.

Shells such as scallop shell, oxyster shell, pearl oxyster shell, etc. are washed thoroughly, and are heated at 1000° C - 1200° C for one hour to remove completely organic materials present in the shell. The organic materials are completely turned into inorganic materials. The major ingredient of the said shell is calcium oxide, and minor ingredients are magnesium, potassium, phosphorous and trace amount of germanium. Whereas, if toxic heavy metals such as mercury, lead, etc. are present in the said mineral, the mineral is chemically treated with carbonate and a fine quality mineral containing no heavy metals can be obtained. When the said mineral is further heated at 1000° C - 1200° C, refined calcium oxide can be obtained.

When calcium oxide obtained by the method described above is dissolved in water, calcium oxide turns into calcium hydroxide showing a strong alkali. Consequently, when the said calcium hydroxide is allowed to react with various food organic acids such as lactic acid, malic acid, citric acid, etc., salts consisting mainly of calcium may be produced.



The said chemical equation is a general form. Whereas, R-COO-H is various organic acids such as lactic acid, malic acid, citric acid, etc.; and (RCOO)₂Ca is salt of organic acid.

A mixture consisting of 3 parts of calcium salt of food organic acids prepared by the manner as described above (a mixture of calcium citrate, calcium malate and calcium lactate; whereas the weight ratio of calcium citrate : calcium malate : calcium lactate is 1 : 1 : 1.), 3 parts of sugars (a mixture of fruit sugar (or levulose) and invert sugar; whereas the weight ratio of fruit sugar : invert sugar is 2 : 1.), 4 parts of natural fruit juice (a mixture of orange juice and lemon juice; whereas, the weight ratio of orange juice : lemon juice is 3 : 1) and 90 parts of water is prepared. In order to add a proper sour taste to the said mixture, a small amount of natural apple vinegar is added to make the pH 4. In addition, a small amount of plant extracts such as extracts of boxthorn, pearl barley, shiitake mushroom (Cortinellus shiitake), etc., and flavoring agents can be added. Thus, a soft drink

having rich in flavor and taste, which is good for the health, can be prepared.

The fore-mentioned case is one of many procedures of preparing calcium enriched soft drink described in the present invention. As a proper daily intake of calcium per day per a person is approximately 600 - 800 mg, the amount of intake of such preparation can be adjusted according to the said standard requirement of calcium. Although it is preferable to use the method of preparing calcium salts of food organic acids described above, calcium salts of food organic acids prepared by other methods may be used.

Since the calcium enriched soft drink described in the present invention is prepared by adding calcium salts of various food organic acids such as calcium citrate, calcium malate, calcium lactate, calcium tartarate, etc., which are profitable to the citric acid cycle of the metabolism, an intake of this preparation generates some resistance to disorders.

Moreover, this preparation is especially good for growing children and infants who require a considerably large amount of calcium.

As calcium salts of organic acids are relatively soluble in water or aqueous solution containing other ingredients, and is very stable, the preparation of mixture is very easy. Although some calcium salts of organic acids have bitter taste when the concentration of the acid is too high, the composition described above (as a practical example) does not interfere the taste and the gustation. Consequently, the said preparation can support the flavor of the drink and can be used for the practical purposes.


**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

 Address COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/0607007	05/07/86	PERCENT	D 3028

☐ CALL BY LETTER
 THE PATENT & GAMBLE COMPANY
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EXAMINER	
PADMAN C. Paden	
ART UNIT	PAPER NUMBER
132	3
DATE MAILED: 12/10/86	

This is a communication from the examiner in charge of your application.
 COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7/31/86 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
 Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-848. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-28 are pending in the application.
 Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-28 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved, ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections **MUST** be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other _____

PTOL-326 (Rev. 7-82)

EXAMINER'S ACTION

PGJ0013912

Art Unit 132
Serial No. 860,607

-2-

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 19-27 are rejected under 35 U.S.C. 103 as being unpatentable over Nakel et al in view of Sperti.

Nakel et al disclose a method of making a beverage wherein an aqueous solution of citric, malic and phosphoric acids is prepared (see embodiment 1). Then calcium carbonate and magnesium carbonate are added. Finally this pre-mix is combined with a beverage syrup. The claims appear to differ from Nakel et al in the recitation of the use of fruit juice specifically and in the use of the specific concentration of acids and calcium employed. Sperti teach citrus juice products which contain calcium chloride, citrates and malic acid (note column 2, lines 46-50). Thus it would be obvious to one of ordinary skill in the art to substitute the orange juice of Sperti for the beverage syrup

Art Unit 132
Serial No. 860,607

-3-

of Nakel et al since both Nakel et al and Sperti are directed to flavored beverages generally. To utilize orange juice specifically in the method of Nakel et al is not seen to constitute unobviousness. It is appreciated that the specific calcium content of the claims is not recited (Nakel et al utilizes 0.04%). However, this variation in calcium content is within the determination of one of ordinary skill in the art of beverage formulation.

It is further appreciated that the use of orange juice in the pre-mix of the claims (claim 23) or sugar (claim 24) is not disclosed however to substitute these ingredients in the premix of Nakel et al is seen to be a matter of choice with respect to premix formulation composition. The use of freezing in claim 27 is a well known expedient in the beverage art.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102 b as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Kaju et al or Aktins et al.

The references are directed to a fortified juice product. The fact that the product may have been made by a different method is not seen to constitution

Art Unit 132
Serial No. 860,607

-4-

unobviousness (see In re Thorpe 227 USPQ 964.

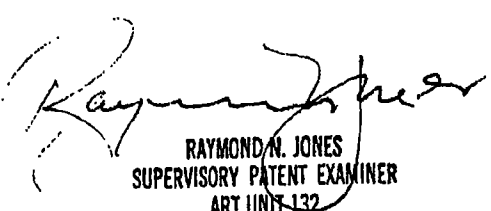
Claims 1-18 are rejected under 35 U.S.C. 103 as being unpatentable over Sperti et al.

Sperti et al is directed to a citrus drink which is formulated with added calcium chloride, sucrose and citrate. The sugar content cited is 10.3° Brix (note column 5, lines 11-20 and 41). Malic acid is cited as a buffer commonly used with orange juice. The claims appear to differ from Sperti et al in the recitation of the specific calcium level utilized and in the recitation of the malic acid to citric acid ratio utilized. Kaji et al teach a calcium fortified carbonated fruit drinks containing 0.6% calcium and a one to one ratio of citrate to malate. It would be obvious to one of ordinary skill in the art to utilize the calcium content and citrate to malate ratio of Kaji in the fruit juice drink of Sperti et al since such a variation appears to within the determination of one of ordinary skill in the art of beverage formulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Paden whose telephone number is (703) 557-9803.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-2475.

Pad 12/5/86
C. Paden:fdc
703-557-9803
12/02/86
12/04/86


RAYMOND N. JONES
SUPERVISORY PATENT EXAMINER
ART UNIT 132

12-9-86

FORM 0-892 (REV. 3-78)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		SERIAL NO. 860607	GROUP ART UNIT 132	ATTACHMENT TO PAPER NUMBER 3						
NOTICE OF REFERENCES CITED				APPLICANT(S) 12-2 Heckert								
U.S. PATENT DOCUMENTS												
	DOCUMENT NO			DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE				
A	3	1	1	4	6	4	1	12/17/63	Spartan	426	599	
B												
C												
D												
E												
F												
G												
H												
I												
J												
K												
FOREIGN PATENT DOCUMENTS												
	DOCUMENT NO			DATE	COUNTRY	NAME	CLASS	SUB- CLASS	PERTINENT SHTS. PP DWG. SPEC			
L												
M												
N												
O												
P												
Q												
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)												
R												
S												
T												
U												
EXAMINER C Paden					DATE 11/25/86							
*A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, section 707.05 (a).)												



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
860607	5/7/86	Heckert	3528

EXAMINER	
Paden	
ART UNIT	PAPER NUMBER
132	4

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Paden / Caroline Callahan (3) Guttas
(2) Golian (4) Heckert

Date of interview March 2, 1987 DukeType: ☐ Telephonic ☒ Personal (copy is given to ☒ applicant ☒ applicant's representative).

Exhibit shown or demonstration conducted: ☒ Yes ☐ No. If yes, brief description: Compared pre-mix procedure with various procedures of direct addition - formal declaration to be filed.

Agreement ☐ was reached with respect to some or all of the claims in question. ☒ was not reached.Claims discussed: 19 as typical of method claims

Identification of prior art discussed: _____

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Pre-mix procedure appears to be preferred or only workable procedure comparing direct addition. Declaration to be filed. First two pages of attachment were discussed.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

☐ Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

JOSEPH GOLIAN
PRIMARY EXAMINER
ART UNIT 132

Carolyn Paden
Examiner's Signature

PTOL-413 (rev. 1-81)

ORIGINAL FOR INSERTION IN RIGHT HAND FLAP OF FILE WRAPPER

Interview for Case 3528

I. Summary of Invention

- A. Objective: supplement products containing at least 45% juice with high levels of calcium (0.05 to 0.26%, preferably 0.10 to 0.15%).

milk .12-.13%

- B. Potential Problems to Solve.

Ca₃ Citrate 2

1. solubilization of calcium.
*above saturation level
or salty*
2. avoid: (a) deterioration of juice quality; (b) addition of unpleasant tasting materials; (c) removal of desirable juice volatiles; and (d) other processing problems (e.g., foaming).
acid above that in juice

- C. Premix Method Achieves Objective and Solves Problems.

1. Claim 19

- a. form at least metastable solution of solubilized calcium from:
 - (1) water
 - (2) malic acid, or preferably mixture of malic and citric acid
 - (3) calcium hydroxide, calcium oxide, or calcium carbonate *soluble in acid*
- b. combine solution of solubilized calcium with concentrated juice

2. Drawing to explain details of premix method.
3. Preferably use premix stabilizers such as sugars, concentrated juice or pectin to keep calcium solubilized in premix solution for extended periods. See Claims 23 and 24.
4. Offer products made by premix method.
 - a. orange
 - b. grapefruit
5. Potential problems caused by direct addition of calcium hydroxide or calcium carbonate to juice/concentrate.
(Demonstration)
 - a. calcium hydroxide
 - (1) very poor calcium solubility in juice/concentrate
 - (2) undesirable color generation
 - (3) undesirable amine odors
 - (4) gelling of product
 - b. calcium carbonate
 - (1) undesirable carbonation and foaming of juice
 - (2) poor calcium solubility in juice/concentrate
 - (3) strip desirable juice volatiles

II. Why Prior Art Doesn't Teach or Suggest Claimed Invention

A. Claims 19-27 (Premix Method), relative to Nakel in view of Sperti.

1. Presolubilization of calcium/acids before addition to juice is not critical to Nakel or Sperti. Nakel primarily directed at carbonated soft drinks which may or may not contain juice. Sperti says salts/acids can be added to: (a) juice/concentrate; (b) water used to extend product; or (c) extended product itself. Sperti even suggests addition to juice/concentrate is preferred (see col. 5, line 70 to col. 6, line 5).
2. Nakel and Sperti are not directed at supplementing juices with high levels of solubilized calcium. Nakel uses a mixture of cations (calcium, potassium and preferably magnesium) to improve mouthfeel (body) of beverages without imparting off-notes of particular cation. Sperti uses a variety of additives in "very small amounts" to improve the flavor of extended juice products. Indeed, Sperti doesn't require calcium as additive (see formula at col. 5, lines 40-62).
3. Nakel and Sperti only disclose low level addition of calcium to beverage products. For Embodiments 1 to 9 of Nakel, calcium level ranges from 0.014 to 0.045%. For Sperti, highest calcium level disclosed is 0.014% (see col. 5, line 15)

4. Scale up of Nakel and Sperti technology to achieve preferred calcium levels (0.10 to 0.15%) would yield beverages having excessive saltiness. Offer juice product containing enough calcium chloride to provide about 0.12% calcium as example.

B. Claim 28 (Calcium-Supplemented Product Made by Premix Method), relative to Aktins or Kaji.

1. Aktins doesn't teach fortification of citrus juice with high levels of calcium (i.e., 0.05% or higher). Fortified citrus juices of Aktins contain low levels of added calcium (maximum of 0.014% based on addition of preferred calcium chloride salt). Maximum permissible amount of calcium salt that Aktins says can be added is 0.04%. This would, in fact, teach away from fortification of citrus juice with high levels of calcium.
2. Kaji doesn't teach calcium fortification of beverages containing significant amounts of juice (i.e., at least 45%). The calcium enriched soft drinks of Kaji contain minimal juice (4% by weight based on Example). No suggestion that Kaji technology applicable to beverages containing much higher levels of juice.

C. Claims 1-18 (Calcium-Supplemented Juice Beverages and Juice Concentrates), relative to Sperti (in view of Kaji?).

1. Calcium chloride addition taught by Sperti satisfactory only for low levels of calcium. Based on adding 0.04% calcium chloride,

as taught in example (see col. 5, lines 9-20), Sperti extended juice products contain only 0.01⁴% calcium. Adding more calcium chloride to achieve higher calcium levels (e.g., 0.10 to 0.15%) will cause excessive saltiness due to high levels of chloride ion (0.18 - 0.27%). Note that Claim 1 specifies maximum of 0.07% chloride. See juice product containing calcium chloride at level of 0.12% calcium.

2. Sperti suggests using mostly citric acid, very little malic acid in extended juice products. Based on example (see col. 5, lines 9-20), Sperti extended juice products contain at least 99% citric acid/citrate combined, and less than 1% malic acid. Note that weight ratio of citric acid:malic acid in Claim 1 is no greater than 90:10. At weight ratio citric acid:malic acid suggested by Sperti, calcium may precipitate out of juice at high levels (e.g., 0.10 to 0.15%).
3. Kaji teaches calcium fortification at too high a level for drinkable juice beverages. The Kaji enriched soft drinks contain 0.6% calcium (calculated). Note that maximum calcium level in Claim 1 is 0.26%. Calcium, at level disclosed by Kaji, will precipitate out, even with 50:50 weight ratio citric acid:malic acid. See reproductions of Kaji drinks.
4. Kaji doesn't teach calcium fortification of products containing significant levels of juice (i.e., at least 45%). Accordingly, applicability of Kaji teachings to Sperti extended juice products questionable.

Case 3528

19. A method for preparing a calcium-supplemented fruit juice product, which comprises the steps of:
 - a. forming an at least meta-stable aqueous premix solution of solubilized calcium from water, an acid component comprising from 0 to about 90% by weight citric acid and from about 10 to 100% by weight malic acid, and a calcium source selected from the group consisting of calcium carbonate, calcium oxide, and calcium hydroxide; and
 - b. combining the premix solution of solubilized calcium with fruit juice material comprising concentrated fruit juice having a sugar content of from about 20 to about 80° Brix, to provide a calcium-supplemented fruit juice product having: (1) at least about 0.05% solubilized calcium; (2) at least about 45% fruit juice; and (3) a sugar content of from about 2 to about 75° Brix.
28. A calcium-supplemented fruit juice product made by the method of Claim 19.
1. A calcium-supplemented single-strength fruit juice beverage, which is substantially free of added protein and which comprises:
 - a. from about 0.05 to about 0.26% by weight solubilized calcium;
 - b. from about 0.4 to about 4% by weight of an acid component comprising a mixture of citric acid and malic acid in a weight ratio of citric acid: malic acid of from about 5:95 to about 90:10;
 - c. at least about 45% fruit juice;
 - d. a sugar content from about 2 to about 16° Brix; and
 - e. no more than about 0.07% by weight chloride ion.



RECEIVED
MAY 27 1987
GROUP 130

CASE 3528

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
In the Application of
DAVID C. HECKERT
Serial No. 860,607
Filed May 7, 1986
FRUIT JUICE BEVERAGES AND
JUICE CONCENTRATES NUTRI-
TIONALLY SUPPLEMENTED WITH CALCIUM

:
: Group Art Unit 132
: Examiner C. Paden

5/20/87
6-1-87

PETITION FOR A TWO MONTH EXTENSION OF TIME
PURSUANT TO 37 CFR 1.136(a)

The Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 CFR 1.136(a), Applicants respectfully request that the response period to the Office Action mailed December 10, 1986, be extended two months through May 10, 1987. Please charge the fee of \$170.00 required in 37 CFR 1.17(b) to Deposit Account No. 16-2480. A duplicate copy of this petition is enclosed.

Respectfully submitted,

DAVID C. HECKERT

By Eric W. Gutttag
Eric W. Gutttag
Attorney for Applicant
Reg. No. 28,853

Cincinnati, Ohio
(513) 659-2736

May 7, 1987

RW10075 05/18/87 860607

16-2480 010 116

170.00CH

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner of Patents & Trademarks,
Washington, D. C. 20231,

on May 7, 1987
Eric W. Gutttag
Eric W. Gutttag
Registration No. 28,853


 IN THE UNITED STATES PATENT & TRADEMARK OFFICE
 RESPONSE/AMENDMENT

Case Docket No. 3528

 Commissioner of Patents and Trademarks
 Washington, D.C. 20231

Dear Sir:

Transmitted herewith is a RESPONSE for the patent application:

Inventor(s): David C. Heckert

Group Art Unit 132

Serial No.: 860,607

Examiner: C. Paden

Date Filed: May 7, 1987

 Title: Fruit Juice Beverages and Juice Concentrates
 Nutritionally Supplemented with Calcium

1. ☐ No additional fee is known to be required.
2. ☒ The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)	OTHER THAN A SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA*	RATE	FEE
TOTAL	29	MINUS	** 28	= 1	x \$12 =	\$12.00
INDEP.	3	MINUS	*** 3	= 0	x \$34 =	\$ 0
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ \$110 =	\$
TOTAL						\$12.00

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the highest number of total claims previously paid for is less than 20, write "20" in this space.

*** If the highest number of independent claims previously paid for is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.

3. ☐ The Commissioner is hereby petitioned under 37 CFR §1.136(a) to grant any extension of time needed for timely response to the Office Action dated _____ in the above-identified application to preserve pendency of said application. The processing fee under 37 CFR §1.17 has been determined as follows: \$ _____ for a _____ month extension of time.
4. The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 16-2480. A duplicate copy of this sheet is attached.
- a. ☒ Any patent application processing fees under 37 CFR §1.16.
- b. ☒ Any patent application processing fees under 37 CFR §1.17.
5. The Commissioner is hereby authorized to make any additional copies of this sheet needed to accomplish the purposes provided for herein and to charge any fee for such copies to Deposit Account No. 16-2480.

 Date: May 7, 1987
 Cincinnati, Ohio

 Eric W. Guttay
 Attorney for Applicant(s)
 Registration No. 28,853
 Tel. No. 513-659-2736

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 on May 7, 1987
 Eric W. Guttay
 Eric W. Guttay



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MAY 21 1987
GROUP 130

CASE 3528

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of

DAVID C. HECKERT :

Serial No. 860,607 :

Group Art Unit 132

Filed May 7, 1986 :

Examiner C. Paden

FRUIT JUICE BEVERAGES AND

JUICE CONCENTRATES NUTRI-

TIONALLY SUPPLEMENTED WITH CALCIUM

2/6
6-1-87
J.B.

6-4-87

AMENDMENT PURSUANT TO 37 CFR 1.111

The Commissioner of Patents

and Trademarks

Washington, D.C. 20231

Dear Sir:

In response to the Office Action mailed December 10, 1986, please amend the above application as indicated below. The response period has been extended through May 10, 1987 by petition for a two-month extension of time pursuant to 37 CFR 1.36(a) and payment of the appropriate fee pursuant to 37 CFR 1.17(b).

IN THE SPECIFICATION

At page 16, line 10, change "(4.4°C)" to -- (4.4°C) -- .

At page 20, line 33, change "1" to -- 2.2 -- .

IN THE CLAIMS

In Claim 23, line 2, change "concentrate" to -- concentrated -- .

Please add new Claim 29 as follows:

a1
29. The method of Claim 21 wherein the premix solution of solubilized calcium further comprises a polysaccharide selected from the group consisting of pectin, algins, hydrolyzed starches and xanthan gum in an amount of from about 0.01 to about 0.05% on a weight/volume basis.

REMARKS

Applicant respectfully requests reconsideration of the above application, as amended. After amendment, Claims 1 to 29 are currently pending in the above application.

Applicant would like to thank Examiners Golian and Paden for permitting Applicant, David C. Heckert, Applicant's associate, Timothy W. Dake, and Applicant's attorney, Eric W. Gutttag, to have an interview with them on

RM100/4 05/18/87 160607

12.00CH

-2-

March 2, 1987. This interview is summarized accurately in the Examiner Interview Summary Record. In this Amendment, Applicant's attorney will elaborate further on some of the specific points made during this interview.

Several minor errors in the specification and Claim 23 have been corrected. Also, new Claim 29 has been added which recites that the premix solution comprises certain polysaccharides in specified amounts. Support for this new Claim can be found from a combined reading of lines 1 to 9 and lines 28 to 30 of page 15 of the specification.

During a telephone conversation with Examiner Paden in January, 1987, Applicant's attorney asked whether copending applications Serial No. 813,744 and Serial No. 860,726 (cited in Applicant's Disclosure Statement dated July 28, 1986) were considered for provisional rejections under 35 USC 103 and for obviousness-type double patenting. The Examiner indicated that the copending patent applications had been considered, but did not create provisional rejections with regard to the subject matter claimed in the above application.

Enclosed with this amendment is a Rule 132 Declaration of Timothy W. Dake, one of the participants at the March 2, 1987 interview. This Declaration describes samples which were offered or shown to the Examiners, as well as demonstrations which were conducted during the interview. This Declaration also describes the paneling of calcium-fortified orange juice samples containing various levels of added chloride. The significance of this Declaration will be discussed further in the appropriate sections of this amendment.

I. The Calcium-Supplemented Juice Products of the Present Invention

The present invention relates to products containing at least 45% juice which are nutritionally supplemented with significant levels of calcium. For drinkable, single-strength juice beverages, the level of solubilized calcium can be from about 0.05 to about 0.26% by weight. See Claims 1-11. Preferred juice beverages contain from about 0.10 to about 0.15% by weight, e.g. milk level. See Claim 8. In addition to drinkable juice beverages, the present invention also relates to calcium-supplemented juice concentrates which can be used to prepare such beverages. See Claims 12 to 18, and in particular Claim 16.

-3-

II. The Premix Method of the Present Invention Provides These Calcium-Supplemented Juice Products, but Without the Problems Caused by Direct Addition of Calcium Sources to Juice or Juice Concentrate.

The calcium-supplemented juice products of the present invention are preferably obtained by using what is referred to as the "premix method." See Claims 19 to 29. In this premix method, an at least meta-stable solution of solubilized calcium is formed from: (1) water; (2) malic acid, or preferably a mixture of malic and citric acid; and (3) calcium hydroxide, calcium oxide, or calcium carbonate. This meta-stable solution of solubilized calcium is combined with concentrated juice, plus other juice materials such as aroma and flavor volatiles, pulp and peel oils, to provide the calcium-supplemented juice products. The Figure for the above application illustrates a preferred embodiment of the premix method where the premix solution is prepared by adding acids to water to form an acid solution to which is then added calcium carbonate or calcium hydroxide (see Claim 20). It is also preferred to use stabilizers such as sugars, concentrated juice or polysaccharides such as pectin to keep the calcium solubilized in the premix solution for extended periods (see Claims 23, 24 and 29).

At the March 2, 1987 interview, calcium-supplemented orange and grapefruit products containing 60% juice made by this premix method were offered to the Examiners. The products shown in photograph 1 attached to the Rule 132 Declaration of Timothy W. Dake are representative of what were offered. As described in paragraph 4 of this Declaration, these products were prepared from the respective calcium-supplemented orange or grapefruit juice concentrates of the present invention. See also paragraph 5 of this Declaration which describes how these orange and grapefruit juice concentrates were prepared according to the premix method of the present invention.

In providing these calcium-supplemented juice products, the premix method of the present invention avoids the potential problems which can be caused by direct addition of calcium sources to juice or juice concentrates. This was amply shown at the interview by demonstrations involving the direct addition of calcium hydroxide or calcium carbonate to orange juice or orange juice concentrate. The demonstrations which took place at this interview are described in paragraphs 6 to 8 of Mr. Dake's Rule 132 Declaration, the results of which are shown in attached photographs 2 and 4.

-4-

Two demonstrations involving the direct addition of calcium hydroxide to orange juice were conducted. These demonstrations are believed to be representative of what occurs during the direct addition of calcium hydroxide to orange juice or orange juice concentrate in a large blend tank typically used in commercial citrus juice operations. These large blend tanks mix the ingredients in such a way that fairly high, localized concentrations of calcium hydroxide can result in the juice or juice concentrate.

In the first demonstration, sufficient calcium hydroxide was added to the orange juice to provide a calcium content, if completely dissolved, of 0.24%. It was very difficult to dissolve the calcium hydroxide in the juice, even with vigorous hand stirring. As shown in photograph 2, the color of the orange juice significantly darkened after calcium hydroxide addition. Indeed, the color of the juice actually became green in color at the interview.

In the second demonstration, sufficient calcium hydroxide was added to the orange juice to provide a calcium content, if completely dissolved, of 0.48%. Like the first demonstration, it was very difficult to dissolve the calcium hydroxide in the juice. As shown in photograph 3, the color of the juice again darkened after calcium hydroxide addition. Also, a gel formed which separated out. It is believed that this gel is the result of pectin in the juice which has been demethoxylated by the hydroxide and then reacted with the calcium. Also, the juice quickly developed a fishy, amine odor. It is believed that this odor is due to the breakdown of proteins and amino acids present in the juice.

The demonstration involving direct addition of calcium carbonate to orange juice concentrate is representative of what would occur in a blend tank typically used in commercial citrus juice operations. In this demonstration, a mixture of calcium carbonate, citric acid and malic acid was added to orange juice concentrate. (If completely dissolved, this would provide a calcium content, total acid level and weight ratio of citric to malic acid within that defined in Claim 12 of the above application.) It was difficult to completely dissolve this mixture of calcium carbonate, citric acid and malic acid in the orange juice concentrate, even with vigorous hand stirring. As shown in photograph 4, the orange juice concentrate foamed considerably after addition of this mixture due to carbon dioxide evolution as the result of the reaction of calcium carbonate with the acids. This foaming would make pumping and further processing of the concentrate difficult.

-5-

To summarize, calcium supplementation of juice products is not as easy as adding calcium to juice. The calcium must be solubilized in the juice. Also, potential problems such as deterioration of juice quality (e.g., color generation and gel formation), the addition or generation of unpleasant-tasting or smelling materials (e.g., odor), the removal of desirable juice volatiles, as well as other processing problems (e.g., foaming), must be avoided. Direct addition of calcium sources does not solve these problems. The premix method of the present invention does.

III. Claims 19 to 27 and 29, which relate to the preparation of calcium-supplemented juice products by forming a premix solution of solubilized calcium and then combining the premix solution with concentrated juice and other juice materials, are unobvious under 35 USC 103 over Nakel et al, even in view of Sperti et al.

The Examiner has rejected Claims 19 to 27 under 35 USC 103 as unpatentable over U.S. Patent 4,551,342 (Nakel et al), in view of U.S. Patent 3,114,641 (Sperti et al). Basically, the Examiner relies on Nakel et al to disclose the preparation of a "premix" from an aqueous solution of citric, malic and phosphoric acid to which calcium carbonate and magnesium carbonate have been added. This "premix" is then combined with a beverage syrup. The Examiner then relies on Sperti et al, which teaches extended citrus juice products containing calcium chloride, citrates and malic acid, to argue that it would be obvious to substitute orange juice for the beverage syrup of Nakel et al "since both Nakel et al and Sperti et al are directed to flavored beverages generally."

Applicant must respectfully disagree. Unlike the claimed premix method of the present invention, presolubilization of calcium and acids before addition to juice is not critical to either Nakel et al or Sperti et al. Nakel et al is primarily directed at carbonated soft drinks which may or may not contain juice. Sperti et al says that their salts and acids can be added to either: (a) the juice or concentrate; (b) the water used to extend their juice products; or (c) the extended juice product itself. Indeed, Sperti et al even suggests addition to the juice or concentrate is preferred (see Column 5, line 70, to Column 6, line 5).

The Examiner recognizes that the juice products obtained by the claimed premix method have a higher calcium content, but argues that this variation is obvious. Applicant must respectfully disagree. Unlike the claimed premix method, Nakel et al and Sperti et al are not directed at supplementing juices

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with high levels of solubilized calcium. Instead, Nakel et al uses a mixture of cations (calcium, potassium and preferably magnesium) to improve mouthfeel (body) of beverages without imparting the off-notes of any particular cation. Indeed, Nakel et al say this mixture of cations is critical to the mouthfeel and taste properties of their beverages. Sperti et al uses a variety of additives in "very small amounts" to improve the flavor of their extended juice products. Indeed, Sperti et al doesn't require calcium as an additive (see formula at Column 5, lines 40 to 62).

As was emphasized at the interview, the claimed premix method of the present invention provides calcium-supplemented juice products having significant levels of calcium, i.e. at least about 0.05% solubilized calcium. By contrast, Nakel et al and Sperti et al only teach low level addition of calcium to beverage products. For Embodiments 1 to 9 of Nakel et al, calcium levels range from 0.014 to 0.045% for carbonated beverages which do not contain juice. In the case of Sperti et al, the highest calcium level disclosed is only 0.014% (see Column 5, line 15).

Moreover, scale-up of the Nakel et al, and especially the Sperti et al technology, to achieve the preferred higher calcium levels (0.10 to 0.15%) desired by the present invention would yield beverages having excessive saltiness. As described in paragraph 9 of Mr. Dake's Rule 132 Declaration, a sample of single-strength orange juice to which calcium chloride had been added was offered to the Examiners. (Calcium chloride is the calcium salt used in the Sperti et al extended juice products.) The amount of calcium chloride added would provide, in the juice, a calcium level of 0.13% and a chloride level of 0.21%. The salty note imparted by this level of chloride was clearly picked up by the Examiners at the interview.

The Examiner also says the use of concentrated orange juice (Claim 23) or sugar (Claim 24) in the premix solution of the claimed method "is seen to be a matter of choice." Applicant must respectfully disagree. As taught at page 15 of the specification, lines 1 to 15, orange juice concentrate and sugar act as crystallization inhibitors to stabilize the calcium malate and especially citrate species in the premix solution. See also new Claim 29 where certain polysaccharides are also used as premix stabilizers. As previously noted, Nakel et al and Sperti et al are not concerned with the presolubilization of calcium prior to addition to juice. Accordingly, these references would not suggest the use of premix stabilizers according to the premix method defined in Claims 23, 24 and 29.

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IV. Claim 28, which defines a calcium-supplemented fruit juice product made by the premix method of the present invention, is novel under 35 USC 102(b) and unobvious under 35 USC 103 over Kaji et al or Aktins et al.

The Examiner has rejected Claim 28 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103 as obvious over Japanese Patent Document 54-8767 (Kaji et al) or U.S. Patent 3,657,424 (Aktins et al). The Examiner says these references are directed to fortified juice products. She further argues that the fact that the product may have been made by a different method doesn't make it unobviousness, citing In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

Applicant agrees, as was held in the Thorpe case, that the patentability of "product-by-process" claims must be based on the product itself. However, Applicant disagrees with the Examiner's position that Kaji et al or Aktins et al disclose, or even suggest, the calcium-supplemented juice products of Claim 28. Kaji et al doesn't teach calcium fortification of beverages containing significant amounts of juice, i.e. at least 45% juice as defined in Claim 28. Instead, the calcium-enriched soft drinks of Kaji et al contain minimal juice (about 4% by weight based on the one example given). Moreover, there is no suggestion that the Kaji technology would be applicable to beverages containing much higher levels of juice.

Aktins et al doesn't teach fortification of citrus juice with high levels of calcium, i.e. about 0.05% or higher as defined in Claim 28. The fortified citrus juices of Aktins et al contain only low levels of added calcium (a maximum of 0.014% based on addition of the preferred calcium chloride salt). Indeed, the maximum permissible amount of calcium salt that Aktins et al says can be added is 0.04% (see Column 2, line 70, to Column 3, line 1). This would, in fact, teach away from fortification of citrus juices with higher levels of calcium, as in the calcium-supplemented juice products of Claim 28.

V. Claims 1 to 18, which define calcium-supplemented juice beverages and juice concentrates which contain high levels of solubilized calcium without the salty note imparted by too high a level of chloride ion, are unobvious under 35 USC 103 over Sperti et al, even in view of Kaji et al.

The Examiner has rejected Claims 1 to 18 under 35 USC 103 as unpatentable over Sperti et al, apparently in view of Kaji et al. The Examiner relies on Sperti et al to teach citrus drinks which are formulated with added calcium chloride, sucrose and citrate and to show that malic acid is a buffer commonly used in orange juice. She further relies on Kaji et al to

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teach calcium-fortified carbonated fruit drinks containing 0.6% calcium and a 1 to 1 weight ratio of citrate to malate. Accordingly, she argues it would be obvious to utilize the calcium level and citric to malic ratio of Kaji et al in the fruit drink of Sperti et al.

Applicant respectfully submits that the calcium-supplemented juice beverages and juice concentrates of Claims 1 to 18 are unobvious over each of these references alone, or in combination. The calcium chloride addition taught by Sperti et al is satisfactory only for low levels of calcium. Based on adding 0.04% calcium chloride as taught in the example at Column 5, lines 9 to 20, the Sperti extended juice products contain only 0.014% calcium. By comparison, the juice beverages of Claims 1 to 12 contain at least about 0.05% solubilized calcium, while the juice concentrates of Claims 13 to 18 contain at least about 0.15% solubilized calcium.

Moreover, adding more calcium chloride to achieve higher calcium levels will cause excessive saltiness due to the resulting higher levels of chloride. This is especially true if sufficient calcium chloride were added to achieve the preferred calcium level of 0.10 to 0.15% defined in Claim 8. If calcium chloride were used as the only calcium source, the level of chloride would be from 0.18 to 0.27%, far higher than the maximum of about 0.07% chloride defined in Claim 1. As was shown at the interview, juice products fortified solely with calcium chloride to achieve milk level calcium (about 0.12%) had a definite salty note imparted by the chloride.

Indeed, juice products fortified to milk level calcium, but only partially with calcium chloride as the source of calcium, impart a recognizable salty note at chloride concentrations above the maximum defined in Claim 1. As described in paragraph 12 of Mr. Dake's Rule 132 Declaration, samples of orange juice containing milk levels of calcium to which have been added 0, 0.043%, 0.086%, and 0.129% chloride (from calcium chloride dihydrate) were paneled. The sample containing 0.043% chloride (below the maximum level defined in Claim 1) was not considered statistically different in terms of salty/brackish taste from the sample containing no added chloride. By contrast, the samples containing 0.086% and 0.129% added chloride (above the maximum level defined in Claim 1) were considered to be statistically more salty/brackish in taste compared to the sample containing no added chloride.

In addition, Sperti suggests using mostly citric acid, and very little malic acid, in their extended juice products. Based on the example given in Column 5, lines 19-20, the Sperti et al extended juice products contain at

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least 99% citric acid/citrate combined, and less than 1% malic acid. The Examiner should note that the weight ratio of citric acid:malic acid defined in Claim 1 is no greater than 90:10. At the weight ratio of citric acid:malic acid suggested by Sperti et al, calcium might precipitate out of the juice at very high levels, e.g., at calcium levels of 0.10 to 0.15% defined in Claim 8.

Kaji et al teaches calcium fortification at too high a level for single-strength beverages. The Kaji et al enriched soft drinks contain, on a calculated basis, 0.6% calcium. By contrast, the maximum calcium level specified for the juice beverages of the present invention in Claim 1 is about 0.26%. Calcium, at the level disclosed by Kaji et al, can precipitate out of single-strength beverages.

The precipitation potential of the Kaji et al enriched drinks is graphically demonstrated by photograph 5 attached to Mr. Dake's Rule 132 Declaration. The Kaji et al samples in the photograph, with and without vinegar, were shown to the Examiners at the interview. As can be seen, even the sample with vinegar, which is made by the preferred method disclosed in Kaji et al, has a brown precipitated solid at the bottom, which is believed to contain calcium citrate. The level of vinegar in this sample is so high as to make it virtually unpalatable. However, as shown by the sample without vinegar, even more material will precipitate out (as calcium citrate) if vinegar is not added.

Applicant also challenges the Examiner's basis for combining the teachings Kaji et al with those of Sperti et al. As previously noted, in part IV of this amendment, Kaji et al doesn't teach calcium fortification of products containing significant levels of juice, i.e., at least 45% juice as defined in Claims 1 to 18. Nor is there any suggestion that the Kaji et al technology would be applicable to beverages containing much higher levels of juice. Accordingly, Applicant questions how the Examiner can even apply the teachings of Kaji et al to the Sperti et al extended juice products.

VI. Conclusion

Applicant respectfully submits that the premix method of Claims 19 to 27 and 29 is unobvious over the prior art relied on. Unlike the claimed premix method of the present invention, presolubilization of calcium and acids before addition to juice is not critical to either Nakel et al or Sperti et al. These references are also not directed as supplementing juices with high level of solubilized calcium. Instead, these references only disclose low level addition of calcium to beverage products. Moreover, scale-up of the Nakel et al, and

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especially the Sperti et al technology, to achieve the preferred higher calcium levels (0.10 to 0.15%) desired by the present invention would yield beverages having excessive saltiness.

Applicant also submits that the calcium-supplemented fruit juice product made by the premix method of the present invention, as defined in Claim 28, is novel and unobvious over the prior art relied on. Kaji et al doesn't teach calcium fortification of beverages containing significant amounts of juice as defined in Claim 28. Aktins et al doesn't teach fortification of citrus juice with high levels of calcium as defined in Claim 28.

Applicant further submits that the calcium-supplemented juice beverages and juice concentrates of Claims 1 to 18 are unobvious over the prior art relied on. Calcium chloride addition taught by Sperti et al is satisfactory only for low levels of calcium. Moreover, adding more calcium chloride to achieve higher calcium levels will cause excessive saltiness due to the resulting higher levels of chloride. Kaji et al teaches calcium fortification at too high a level for single-strength beverages. Moreover, since Kaji et al doesn't teach calcium fortification of products containing significant levels of juice, Applicant challenges the Examiner's basis for combining the teachings of this reference with those of Sperti et al.

For these reasons, Applicant respectfully requests that a patent be allowed to issue on Claims 1 to 29 currently pending in the above application.

Respectfully submitted,

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